

## **REMARKS**

Claims 1, 2 4, 5, 7, 9, 11, 13, 15, 16, 21-26, 28-31, and 37 have been canceled without prejudice or disclaimer. Claims 38-87 have been added and therefore are pending in the present application. Claims 38-87 are supported throughout the specification, including the original claims.

The specification has been amended to delete embedded hyperlinks, as requested by the Examiner.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. The Objection to Claims 7, 9 and 11**

The Office objected to claims 7, 9, and 11 because they fail to recite the positions in numerical order.

Claims 7, 9, and 11 have been canceled without prejudice or disclaimer. Furthermore, the newly presented claims recite the positions in numerical order. Applications therefore submit that this objection has been overcome.

### **II. The Rejection of Claim 30 under 35 U.S.C. 101**

Claim 30 is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. In particular, the Office stated that claim 30 is a method claim which does not recite any steps.

Claim 30 has been canceled without prejudice or disclaimer. Furthermore, the newly presented method claims recite steps. Applicants therefore submit that this rejection has been overcome.

### **III. The Rejection of Claims 15, 16, and 30 under 35 U.S.C. 112**

Claims 15, 16, and 30 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office objected to (1) the term “preferably” recited in claims 15 and 16; (2) claim 30 as being incomplete; and (3) the lack of antecedent basis for the recitation “wherein the protease of claim 1” in claim 30.

Claims 15, 16, and 30 have been canceled without prejudice or disclaimer. Furthermore, the newly presented claims do not use the term “preferably” or the recitation “wherein the protease”. Furthermore, the newly presented method claims are complete. Applicants therefore submit that this rejection has been overcome.

#### **IV. The Rejection of Claims 1, 2, 4, 16, and 21 under 35 U.S.C. 102**

Claims 1, 2, 4, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriyama et al. (JP 2003-284571). This rejection is respectfully traversed.

Moriyama et al. published on October 7, 2003, less than one year before Applicants' effective US filing date of October 10, 2003. Therefore, Moriyama et al. is not prior art under 35 U.S.C. 102(b).

Moreover, according to the Office, Moriyama et al. disclose the amino acid sequence of the mature *Nocardiopsis* sp. TOA-1 protease, which has 89% sequence identity to SEQ ID NO: 2 of the present invention.

However, the *Nocardiopsis* sp. TOA-1 protease is a wild-type protease, not a variant. Moreover, Moriyama et al. do not disclose variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

The Office also states that "Because the instant application indicates at page 8, lines 23-24, that a 'variant' protease is a protease that is not identical to SEQ ID NO: 2 herein, the protease of SEQ ID NO: 2 of Moriyama et al. meets the limitations of claims 1, 2, 4, and 16 herein." This is respectfully traversed.

Page 8, lines 24-25 merely states that the sequence of amino acids 1-188 of SEQ ID NO: 2 is not a variant in accordance with the present invention. This is not a definition of a variant of the present invention. Indeed, the specification identifies a number of proteases, which are not variants in accordance with the invention. See page 8, line 23 – page 9, line 3.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of Claims 1, 2, 4, 16, and 28-31 under 35 U.S.C. 102**

Claims 1, 2, 4, 16, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Shøholm et al. (WO 01/58276 and U.S. Patent No. 6,855,548). This rejection is respectfully traversed.

Shøholm et al. (U.S. Patent No. 6,855,548) published on February 15, 2005, after Applicants' effective US filing date of October 10, 2003. Therefore, Shøholm et al. (U.S. Patent No. 6,855,548) is not prior art under 35 U.S.C. 102(b).

Moreover, according to the Office, Shøholm et al. disclose the amino acid sequence of a *Nocardiopsis* sp. NRRL 18262 protease, which has 99.5% sequence identity to SEQ ID NO: 2 of the present invention.

However, the *Nocardiopsis* sp. NRRL 18262 protease is a wild-type protease, and not a variant. Moreover, Shøholm et al. do not disclose variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

As explained above, the Office is incorrect that the present application defines a variant protease as a protease that is not identical to SEQ ID NO: 2 herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VI. The Rejection of Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 under 35 U.S.C. 102**

Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by over Lassen et al. (U.S. Patent No. 7,179,630). This rejection is respectfully traversed.

According to the Office, Lassen et al. disclose the amino acid sequence of a *Nocardiopsis* sp. DSM 43235 protease, which has 87.4% sequence identity to SEQ ID NO: 2 of the present invention.

However, the *Nocardiopsis* sp. DSM 43235 protease is a wild-type protease, not a variant. Moreover, Lassen et al. do not disclose variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

As explained above, the Office is incorrect that the present application defines a variant protease as a protease that is not identical to SEQ ID NO: 2 herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VII. The Rejection of Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 under 35 U.S.C. 102 and 103**

Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lassen (U.S. Patent No. 7,485,447). Claims 1, 2, 4, 9, 15, 16, 21-25, 28-31,

and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Lassen (U.S. Patent No. 7,485,447). These rejections are respectfully traversed.

According to the Office, Lassen discloses the amino acid sequences of a *Nocardiopsis prasina* DSM 15648 protease, a *Nocardiopsis prasina* DSM 15649 protease, and a *Nocardiopsis alba* DSM 15647 protease, which have a sequence identity of 98.6%, 99.4%, and 87.4%, respectively, to SEQ ID NO: 2 of the present invention.

However, the *Nocardiopsis prasina* DSM 15648, *Nocardiopsis prasina* DSM 15649, and *Nocardiopsis alba* DSM 15647 proteases are wild-type proteases, not variants. Moreover, Lassen does not disclose variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

As explained above, the Office is incorrect that the present application defines a variant protease as a protease that is not identical to SEQ ID NO: 2 herein.

The Office also stated that "Lassen et al. are considered to inherently disclose the following amino acid substitutions in the amino acid sequence of SEQ ID NO: 2 indicated by claims 1, 2, 4, 7, 9, 15, and 16 herein...." This is respectfully traversed.

Applicants respectfully disagree that Lassen et al. disclose that amino acid substitutions in a position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131.

Moreover, Lassen qualifies as prior art solely under 35 U.S.C. 102(e). Applicants therefore submit the following showing under 35 U.S.C. 103(c), which is in accordance with the "Guidelines Setting Forth A Modified Policy Concerning The Evidence Of Common Ownership, Or An Obligation Of Assignment To The Same Person, As Required By 35 U.S.C. 103(c)", set forth in the Official Gazette (December 26, 2000). Applicants hereby confirm that the instant application and Andersen (WO 02/31124) were, at the time the invention of the instant application was made, owned by or subject to an obligation of assignment to Novozymes A/S. Thus, Lassen cannot be relied on in a rejection under 35 U.S.C. 103.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under 35 U.S.C. 102 and 103. Applicants respectfully request reconsideration and withdrawal of the rejections.

#### **VIII. The Rejection of Claims 22-25, 28-31, and 37 under 35 U.S.C. 103**

Claims 22-25, 28-31, and 37 are rejected under 35 U.S.C. 103 as being unpatentable over Moriyama et al. (JP 2003-284571) in view of Wilson et al. (U.S. Patent No. 5,705,379), Anderson et al. (EP 0506448) and Sjøholm et al. (WO 01/58276). This rejection is respectfully traversed.

As explained above, Moriyama et al. and Sjøholm et al. do not teach or suggest variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

Wilson et al. and Anderson et al. also do not teach or suggest variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IX. The Rejection of Claims 21-25 and 37 under 35 U.S.C. 103**

Claims 21-25 and 37 are rejected under 35 U.S.C. 103 as being unpatentable over Sjøholm et al. (WO 01/58276) in view of Wilson et al. (U.S. Patent No. 5,705,379) and Anderson et al. (EP 0506448). This rejection is respectfully traversed.

As explained above, Sjøholm et al., Wilson et al., and Anderson et al. do not teach or suggest variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **X. The Rejections of Claims under the Doctrine of Obviousness-Type Double Patenting**

Claims of the present application are rejected under the doctrine of obviousness-type double patenting as follows:

1. Claim 30 as being unpatentable over claims 1-6 of Sjøholm et al. (U.S. Patent No. 6,855,548);

2. Claims 1, 2, 4, 16, 21-25, 31, and 37 as being unpatentable over claims 1-6 of Sjøholm et al. (U.S. Patent No. 6,855,548) in view of Wilson et al. (U.S. Patent No. 5,705,379) and Anderson et al. (EP 0506448);

3. Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 as being unpatentable over Lassen et al. (U.S. Patent No. 7,179,630);

4. Claims 21-25 as being unpatentable over Lassen et al. (U.S. Patent No. 7,179,630) in view of Wilson et al. (U.S. Patent No. 5,705,379);

5. Claims 1, 2, 4, 11, 15, 16, 28-31, and 37 as being unpatentable over Lassen et al. (U.S. Patent No. 7,208,310);

6. Claims 21-25 as being unpatentable over Lassen et al. (U.S. Patent No. 7,208,310) in view of Wilson et al. (U.S. Patent No. 5,705,379);

7. Claims 1, 2, 4, 11, 15, 16, 21-25, and 28-31 as being unpatentable over Lassen (U.S. Patent No. 7,485,447);

8. Claim 37 as being unpatentable over Lassen (U.S. Patent No. 7,485,447) in view of Anderson et al. (EP 0506448);

9. Claims 1, 2, 4, 11, 15, 16, 21-25, 28-31, and 37 as being unpatentable over Ooestergaard et al. (U.S. Patent No. 7,588,926);

10. Claims 1, 2, 4, 11, 15, 16, 21-25, and 28-31, as being unpatentable over U.S. Application No. 11/570,193 [sic, 11/570,913]; and

11. Claim 37 as being unpatentable over U.S. Application No. 11/570,193 [sic, 11/570,913] in view of Anderson et al. (EP 0506448).

These rejections are respectfully traversed.

None of the cited references teaches or suggests variants comprising a substitution in at least one position selected from the group consisting of 78-81; 83-100; 103-106; 111-114; and 118-131; wherein the variant has a sequence identity to the sequence of amino acids 1 to 188 of SEQ ID NO: 2 of at least 90% but less than 100%, as claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under the doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration and withdrawal of the rejections.

## **XI. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

Date: June 2, 2010

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